REMARKS

Status of Claims

Claims 1, 2 and 4-22 are pending in this application. Claims 18 and 21 are canceled herein without prejudice. Claims 20 and 22 are amended herein. Support for the claim amendments is provided by the specification at, e.g., page 53, second paragraph. No new matter is added by way of these amendments. Entry of the claim amendments and reconsideration in view of the following remarks are respectfully requested.

Information Disclosure Statement

In view of the number of references contained in the Information Disclosure Statement (IDS) filed May 6, 2009, the Examiner has requested that the Applicants point out the most relevant references. Applicants respectfully note that the majority of the documents cited in the IDS either relate to copending applications or to documents which relate to the natural products biphenomycin A or B. It is therefore very difficult to identify documents which seem to be more relevant than other documents.

In view of this, the Applicants have identified the following documents that do not directly relate to biphenomycin or compounds of a similar basic structure as having reduced relevance:

22: Allen and Danishefsky et al. *J. Prakt Chern* (2000) 342:736-744

23: Bajusz et al. *Bioorg. Med. Chem. Lett.* (1998) 8:1477-1482

24: Brands et al. *Bioorg. Med Chem Lett.* (2003) 13:241-246

35: Greene and Wuts, PROTECTIVE GROUPS IN ORGANIC SYNTHESIS

36: Giroux et al. *Tetrahedron Lett.* (1997) 38(22):3841-3844

37: Gupta, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS

41: lshiyama et al. *J. Org Chem* (1995) 23:7508-7510

42: Jorgensen and Gautun *Tetrahedron* 55 (J 999) 10527-10536

45: Miyaura et al. *Chem. Ref* (1995) 95:2457-2483

46: Mueller and BIobel 1984 *PNAS* 81 7421-7425

47: NCCLS for clinical and laboratory standards 5th edition 2000 document M7 - A5 vol. 20 No.2

50: Popienic and Pratt, *Anal Biochem* (1987) 165(1):108-113

52: Rompp *Lexikon Chemie* - version 2.0

53: Rudolph et al. *Org Lett* (2001) 3(20):3153-3155

60: Sobirov et al. *Russian J Bioorg Chem* (1994) 20:397-405

65: Watanabe et al. *Synlett* (1992) 3:207-210

66: Zhao and Moore *J Org Chem* (2002) 67:3548-3554

Applicants further note that the following sets of documents belong to the same patent families, respectively: documents 2 and 15; documents 3 and 14; documents 4, 7 and 16; documents 5, 6, 9, 10 and 13; and documents 8 and 19.

Applicants hope that the information provided above will reduce the burden on the Examiner.

Applicants confirm that all references disclosed in the specification have been properly submitted in an Information Disclosure Statement.

Copending Applications

The following copending applications are brought to the Examiner's attention:

U.S. Application No. 11/904,550 (U.S. Publication No. 2008/0300231)

U.S. Application No. 11/906,088 (U.S. Publication No. 2008/0275018)

U.S. Application No. 12/008,662 (U.S. Publication No. 2008/0306040)

Rejections under 35 U.S.C. 101

Claim 20 stands rejected under 35 U.S.C. § 101 as allegedly drawn to nonstatutory subject matter.

Claim 20 is amended herein to relate to a method for producing a medicament. Support for the amended claim is provided by the specification at, e.g., page 53, second paragraph. Accordingly, this basis for rejection is overcome and may be properly withdrawn.

Rejections under 35 U.S.C. 112, first paragraph

Claims 18, 19 and 21-22 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Office has objected to the inclusion of "treatment and/or prophylaxis of disease" in claims 18 and 21 as overly broad and including any disease. Claims 18 and 21 are canceled herein, rendering the rejection moot with respect to these claims. Applicants respectfully traverse the rejection of claims 19 and 22.

Claim 19 relates to a medicament comprising at least one compound as claimed in claim 1 in combination with at least one pharmaceutically acceptable carrier or other excipient. Such medicaments are disclosed in the specification, at, e.g., pages 165 and 166. Furthermore, the specification discloses that compounds of the invention are pharmacologically active. Claim 22 is amended herein for clarity to relate to a method for *treating* bacterial infections. The specification discloses that compounds of the invention are suitable for combating bacterial infections, and also discloses their use in such methods. Accordingly, claims 19 and 22 satisfy the written description requirement.

In view of the foregoing remarks, Applicants respectfully request that the rejections under 35 U.S.C. 112, first paragraph be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 1-19, 21 and 22 remain rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Clerc et al. (U.S. Patent 5,840,682) for reasons of record. Briefly, the Examiner states that Clerc et al. discloses structurally similar antibacterial compounds which embrace the presently claimed invention. In particular, the Examiner points to compounds of formula (I) wherein R is defined as NH-CH_2-COOH (column 1, lines 21-22) and m, n and p are 0 as rendering obvious compounds of the present invention wherein R^6 is hydrogen and R^5 is alkyl which can be substituted by carboxy. Applicants respectfully traverse the rejections for reasons of record, as well as at least the following reasons.

The Examiner asserts that it would have been obvious to prepare compounds falling within the genus disclosed by Clerc et al. and that one of ordinary skill would have been motivated to select the claimed compounds because they are said to be suggested by the genus as a whole. The Examiner asserts that the disclosure of a genus of useful compounds is sufficient to render a species falling within the genus *prima facie* obvious. Applicants respectfully disagree.

Applicants respectfully submit that, in maintaining the obviousness rejections, the Office has overlooked several key features that differentiate the present invention from the cited art. While the compounds of Clerc et al. might bear some superficial resemblance to the compounds of the present invention, Applicants respectfully submit that the differences between the two groups of compounds are such that the compounds of the invention as a whole cannot be considered obvious in view of Clerc et al.

As the Federal Circuit recently reaffirmed in *Eisai v. Dr. Reddy's Laboratories Ltd.,* 87 USPQ.2d 1452 (Fed. Cir. 2008), in chemical compound cases, "[o]bviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a

particular way to achieve the claimed compound. *Id.* at 1455 (citing *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007)).

In order to establish a *prima facie* case for obviousness for a chemical compound, the Office must first provide a reasoned identification of a "lead compound", and then provide a motivation that would lead one of ordinary skill in the art to modify the lead compound in a particular way to achieve the compounds claimed by the Applicants. The Office has done neither in this case.

First, Clerc et al. do not disclose compounds having antibacterial activity. As indicated by the title, the compounds disclosed in Clerc et al. are peptide antagonists of neurotensin. See also, column 5, lines 63 to 65. One of ordinary skill in the art would not have expected neurotensin antagonists to be a good starting point for the development of compounds having antibacterial activity. The Examiner has provided no basis for the selection of such compounds as lead compounds for the development of novel antibacterial agents, as claimed, and therefore the compounds of the present invention must be considered non-obvious over Clerc et al.

Moreover, there are major structural differences between the compounds of the present invention and those disclosed by Clerc et al. Applicants respectfully submit that these differences are sufficient render the invention as claimed non-obvious over Clerc et al.

First, all of the compounds disclosed by Clerc et al. contain a bicyclic ring system, whereas the compounds of the present invention are monocyclic systems. Specifically, the compounds of Clerc et al. contain a second macrocycle linking the right-hand phenyl ring of the biphenyl moiety with a phenoxy group at the position corresponding to-NR^5R^6 in the instant claims. Such bicyclic compounds are not encompassed by the claims of the present invention. This is such a major structural difference that the compounds of the present invention must be considered non-obvious over Clerc et al.

Further, the compounds of Clerc et al. contain a completely different substitution pattern on the biphenyl backbone from the pattern displayed by the claimed invention. In the present invention, both phenyl groups of the biphenyl backbone bear a hydroxyl or substituted hydroxyl

group at the position para to the biphenyl bond. The compounds of Clerc et al. are unsubstituted at these positions (i.e., in addition to the other differences, OR^7 and OR^8 in the claimed compositions are replaced by hydrogen in Clerc et al.).

Finally, the compounds of Clerc et al. carry a phenoxy group in the 5-position of the biphenyl backbone that forms part of the second macrocyclic ring, and also contain further non-hydrogen substituents in 5- and 6-positions, respectively, on the two phenyl rings that make up the biphenyl backbone. In the compounds of the present invention, these positions are all defined to be hydrogen.

Thus, there are at least three major structural differences between the compounds of the present invention and the compounds of Clerc et al. Therefore, even if one of skill in the art seeking to develop new pharmacologically active compounds started from the compounds of Clerc et al., the structural differences are such that the compounds of the present invention cannot be considered obvious over the compounds of Clerc et al.

The Applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness in the instant case. Accordingly, the Applicants respectfully request that the rejections under 35 U.S.C. § l03(a) be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no.*. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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